EXHIBIT 15

Section 20 – Hepatitis C Protocol

A. Introduction

1. This Hepatitis C Protocol for the Pennsylvania Department of Corrections (PA DOC) provides clinical guidelines for the diagnosis, management, and treatment of inmate patients with chronic Hepatitis C Virus (HCV). HCV is a slowly progressive disease, usually requiring more than 20-40 years to progress to cirrhosis; however, the natural history of HCV is variable and not all patients with chronic HCV will develop cirrhosis during their lifetime. Before a patient develops cirrhosis, the short-term risk of a liver-related complication is low. Once a patient progresses to compensated cirrhosis, there is a higher risk of developing decompensated cirrhosis and or hepatocellular carcinoma (HCC).

2. The goal of Hepatitis C anti-viral treatment is to achieve a sustained virological response (SVR), defined as undetectable HCV virus in the blood, 12 or more weeks after completing anti-viral treatment. Achieving an SVR among patients with compensated cirrhosis reduces the risk of developing decompensated cirrhosis and HCC. Thus, patients with cirrhosis are more likely to have a morbidity and mortality benefit from an SVR and require more urgent need for DAA (Direct Acting Antivirals) treatment (for content reference, please see **Subsection J.1. below**).

B. Screening

1. All new intakes will be screened at their home institutions utilizing the Hepatitis C Antibody test. Anyone may refuse testing by signing a **DC-462, Release from Responsibility for Medical Treatment Form.**

2. The Infection Control Nurse (ICN) will review positive antibody results with all inmates, whether it be at intake or later during incarceration. The Medical Director/designee will order a confirmatory Hepatitis C Ribonucleic Acid (RNA) Quantitative Polymerase Chain Reaction (PCR) test (viral load). Recommended immunizations, counseling, and literature will be provided during that encounter.

3. The ICN shall advise each patient regarding the DOC's Hepatitis C Protocol relating to the documentation of tattoos, positive drug screens, and non-adherence with medical regimens and have the inmate sign a **Hepatitis C Anti-Viral Treatment Protocol Acknowledgement Form (Attachment 20-A)**. If the inmate refuses to sign the form, the ICN shall follow the instructions noted on the form. The Site ICN shall also sign the form.

4. Inmate patients with documented (+) Hepatitis C Antibody test should not be retested, but entered into tracking.

5. Inmate patients who have a documented undetectable Hepatitis C Quantitative PCR may become re-infected while out on parole. If they return to the PA DOC, the Medical Director/designee shall order a repeat viral load on intake.

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C. Tracking

For all patients with a positive HCV antibody test, the ICN will maintain a current **Hepatitis C Tracking Spreadsheet (Attachment 20-B)** in Excel format. This spreadsheet will be forwarded to the Bureau of Health Care Services (BHCS) Infection Control Coordinator (ICC) on a monthly basis.

D. Diagnosing Cirrhosis (for content reference, please see Subsection J.2. below)

1. Assessing for cirrhosis is important for prioritizing inmates for treatment of HCV and in determining the need for additional health care interventions. Cirrhosis may be diagnosed in several ways:

   a. Symptoms and signs that support the diagnosis of cirrhosis may include: Low albumin or platelets, elevated bilirubin or International Normalized Ratio (INR), ascites, esophageal varices, and hepatic encephalopathy. However, isolated lab abnormalities may require additional diagnostic evaluation to determine the etiology.

   b. The AST (Aspartate Aminotransferase) to Platelet Ratio Index (APRI) score is the DOC-preferred initial method for non-invasive assessment of hepatic fibrosis and cirrhosis:

      (1) An APRI score ≥ 2.0 may be used to predict the presence of cirrhosis. At this cutoff, the APRI score has a sensitivity of 48%, but a specificity of 94%, for predicting cirrhosis. Inmates with an APRI score ≥ 2.0 should have an abdominal ultrasound performed to identify other findings consistent with cirrhosis (see abdominal imaging studies below in this list). Lower APRI scores have different sensitivities and specificities for cirrhosis. For example, an APRI score ≥ 1 has a sensitivity of 77% and a specificity of 75% for predicting cirrhosis.

      (2) An APRI score is not necessary for diagnosing cirrhosis if cirrhosis has been diagnosed by other means.

      (3) The APRI may also be used to predict the presence of significant fibrosis (stages 2 to 4, out of 4). Using a cutoff of ≥ 1.5, the sensitivity is 37%, and specificity is 95% for significant fibrosis.

      (4) A single APRI score should not be used in isolation. There are multiple medications and conditions that can result in a transient elevation of AST.

      (5) The APRI score may be invalidated in cases of splenectomy.

2. Liver biopsy is no longer required unless otherwise clinically indicated. However, the presence of cirrhosis on a prior liver biopsy may be used to meet the DOC criteria for HCV treatment.

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3. Abdominal imaging studies such as ultrasound or computerized tomography (CT) scan may identify findings consistent with or suggestive of the following: cirrhosis (nodular contour of the liver), portal hypertension (ascites, splenomegaly, varices), or hepatocellular carcinoma (HCC).

E. Assessing Hepatic Compensation (for content reference, please see Subsection J.2. below)

1. Assessing hepatic compensation is important for determining the most appropriate HCV treatment regimen to be used. The recommended HCV treatment regimen may differ depending on whether the cirrhosis is compensated or decompensated.

2. The CTP (Child-Turcotte-Pugh) score is a useful tool to help determine the severity of cirrhosis and is used by the American Association for the Study of Liver Diseases (AASLD) to distinguish between compensated and decompensated liver disease in patients with known or suspected cirrhosis.

   a. CTP calculator available in the Resource Section of the electronic health record.

   b. The CTP score includes five parameters (albumin, bilirubin, INR, ascites, and hepatic encephalopathy), each of which is given a score of 1, 2, or 3. The sum of the five scores is the CTP score, which is classified as shown in the table below:

CTP SCORE	CTP CLASS	HEPATIC COMPENSATION
5–6	Class A	Compensated cirrhosis
7–9	Class B	Decompensated cirrhosis
≥ 10	Class C	

   c. A CTP score of 5 or 6 is considered to be compensated cirrhosis, while a score of 7 or greater is considered decompensated.

      (1) Warfarin anticoagulation will invalidate CTP calculations if the INR is 1.7 or higher.

      (2) It is recommended that cases of decompensated cirrhosis be managed in consultation with a clinician experienced in the treatment of this condition because the dosages of DAA medications are not well-established with significant hepatic impairment.

F. Additional Interventions for Inmates with Cirrhosis: (for content reference, please see Subsection J.2. below)

1. Pneumococcal vaccine: Offer to all HCV-infected inmates with cirrhosis who are 19 through 64 years of age.

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2. HCC screening: Liver ultrasound is recommended every six months for patients with both cirrhosis and chronic HCV infection.

3. Esophageal varices screening: Screening for esophageal and gastric varices with esophagogastroduodenoscopy (EGD) is recommended for patients diagnosed with cirrhosis.

4. Other healthcare interventions recommended for patients with cirrhosis may include:

   a. Nonselective beta blockers for prevention of variceal bleeding in patients with esophageal varices.

   b. Antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis.

   c. Optimized diuretic therapy for ascites.

   d. Lactulose and rifaximin therapy for encephalopathy.

5. In general, Non-Steroidal Anti-Inflammatory Drugs (NSAID) should be avoided in advanced liver disease/cirrhosis, and metformin should be avoided in decompensated cirrhosis. The detailed management of cirrhosis is beyond the scope of these guidelines. Other resources should be consulted for more specific recommendations related to this condition.

G. Chronic Care Clinic

1. All patients who have chronic Hepatitis C (confirmed by a detectable viral load) will be entered into the Liver Disease Chronic Care Clinic. The ICN will confer with the Site Medical Director to determine if the patient's diagnosis is:

   a. F0-F2 (no fibrosis, mild fibrosis, or moderate fibrosis). All cases not documented F3 or F4.

   b. F3 (advanced fibrosis). Documented by liver biopsy or elastography.

   c. F4 (cirrhosis). See **Subsection D. above.**

2. Patients who are antibody positive only (confirmed by an undetectable viral load) do not have chronic Hepatitis C and will be followed in Chronic Care Clinic at the discretion of the Site Medical Director, if the patient exhibits signs or symptoms of liver disease. Patients who have been treated with medication will continue to be followed in Chronic Care Clinic, whether or not they achieved a SVR.

3. At a minimum, the following will be documented in a Progress Note during the Chronic Care Clinic encounter:

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a. Subjective:

(1) symptoms of cirrhosis or liver failure;

(2) history of ascites, encephalopathy, or esophageal varices (bleeding or not);

(3) estimated date of contracting the disease; and

(4) any recent admissions to the Infirmary, emergency room (ER), or hospital.

b. Objective:

(1) vital signs, weight, and Body Mass Index (BMI);

(2) examination of the sclera for jaundice;

(3) examination of the abdomen, including both ascites and the size and character of either hepatomegaly or splenomegaly;

(4) examination of the skin for changes suggestive of cirrhosis (jaundice, spider angiomata/telangiectasia, palmar erythema, and caput medusae);

(5) examination of the neurological system for the presence of asterixis ("liver flap");

(6) fibrosis stage, if known, and method used to determine the fibrosis stage (e.g. liver biopsy or elastography);

(7) calculation of the APRI, using the calculator located in the Resource Section of the electronic health record;

(8) calculation of the Model of End Stage Liver Disease (MELD) score and the CTP score for patients with cirrhosis, using the calculator located in the Resource Section of the electronic health record;

(9) review of any results of the EGD, elastography, or abdominal ultrasound; and

(10) examination of pertinent laboratory results.

c. Assessment:

(1) F0-F2 (no fibrosis, mild fibrosis, or moderate fibrosis);

(2) F3 (advanced fibrosis); or

(3) F4 (cirrhosis).

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d. Plan of Treatment:

(1) schedule the follow-up Clinic appointment according to the assessment:

(a) F0-F2 (six months);

(b) F3 (three months); or

(c) F4 (one month).

(2) diagnostics ordered will include the following:

(a) initial Chronic Care Clinic for all patients: Comprehensive Metabolic Profile (CMP), Complete Blood Count (CBC), Chronic Hepatitis Panel, and Prothrombin Time (PT)/INR;

(b) yearly labs for all patients: CMP, CBC, and PT/INR.

(c) every six month labs for patients with cirrhosis (F4): CMP, CBC, PT/INR and abdominal ultrasound to evaluate for HCC;

(d) every six month labs for patients without cirrhosis (F0-F3): Liver Function Tests (LFTs) and CBC; and

(e) monthly visits for patients with cirrhosis (F4): No labs required.

4. If the APRI > 1.5 or the Platelet Count is < 100,000/mcL, notify the ICN.

H. Evaluation for Treatment with Anti-Viral Medication

1. The PA DOC will utilize the Federal Bureau of Prisons (FBOP) Priority Criteria as listed in the "Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection Clinical Practice Guidelines, April 2016." (please refer to **Subsection J.2. below**)

2. Determining whether PA DOC priority criteria for treatment are met is an important part of the initial evaluation and ongoing management of inmates with chronic HCV infection. Although all patients with chronic HCV infection may benefit from treatment, certain cases are at higher risk for complications or disease progression and require more urgent consideration for treatment.

3. The PA DOC will use Shear Wave Elastography to determine fibrosis scoring for patients without a diagnosis of cirrhosis who have an APRI > 1.5, a platelet count < 100,000/mcL, or select patients as clinically indicated.

4. The DOC has established priority criteria to ensure that those with the greatest need are identified and treated first (for content reference, please see **Subsection J.2. below**).

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The DOC Chief of Clinical Services will provide periodic guidance on specific strategies for implementing these priority levels:

a. Priority Level 1 – Highest Priority for Treatment

(1) Cirrhosis

(a) This includes cases of known cirrhosis or clinical findings consistent with cirrhosis.

(b) Cases of decompensated cirrhosis with a CTP score of ≥ 7 should receive the highest priority for treatment.

(c) Patients with an isolated APRI score ≥ 2 with no other clinical findings of cirrhosis are included in Priority Level 2.

(2) Liver Transplant Candidates or Recipients

Other types of transplant candidates or recipients may be appropriate to prioritize for treatment and will be considered individually on a case-by-case basis.

(3) Hepatocellular Carcinoma (HCC)

(a) At least one third of all cases of HCC occur in association with HCV infection, with most cases occurring in those with advanced fibrosis or cirrhosis.

(b) Current guidelines do not address the role of HCV treatment in the management of HCC.

(c) HCV treatment in HCC cases will be determined individually and require consultation with an appropriate specialist.

(4) Comorbid Medical Conditions Associated with HCV, including:

(a) Cryoglobulinemia with renal disease or vasculitis; and/or

(b) certain types of lymphomas or hematologic malignancies.

(5) Chronic Kidney Disease with glomerular filtration rate (GFR) < 30 mL/min per 1.73 m^2, including dialysis patients.

(6) Immunosuppressant Medication for a Comorbid Medical Condition

Some immunosuppressant medications (e.g., certain chemotherapy agents and tumor necrosis factor inhibitors) may be needed to treat a comorbid

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medical condition, but are not recommended for use when infection is present. However, data are insufficient and current guidelines are inconsistent regarding treatment of HCV infection in this setting. Such cases will be considered for HCV treatment on an individual basis.

(7) Continuity of Care for those already started on treatment, including inmates who are newly incarcerated in the DOC.

b. Priority Level 2 – High Priority for Treatment

(1) APRI score ≥ 2.

(2) Advanced fibrosis on liver biopsy (e.g., Metavir Stage 3 bridging fibrosis).

(3) Hepatitis B Virus (HBV) coinfection.

(4) Human Immunodeficiency Virus (HIV) coinfection.

(5) Comorbid liver diseases (e.g., autoimmune hepatitis, hemochromatosis, steatohepatitis, etc.).

(6) Chronic kidney disease (CKD) with GFR 30–59 mL/min per 1.73 m^2 (calculated at least twice at one month intervals).

c. Priority Level 3 – Intermediate Priority for Treatment

(1) Stage 2 fibrosis on liver biopsy.

(2) APRI score 1.5 to < 2.

(3) Diabetes mellitus.

(4) Porphyria cutanea tarda.

d. Priority Level 4 – Routine Priority for Treatment

(1) Stage 0 to stage 1 fibrosis on liver biopsy.

(2) All other cases of HCV infection meeting the eligibility criteria for treatment, as noted below under **Subsection H.4.f. below**, "Other Criteria for Treatment."

e. Exceptions to the above criteria for Priority Levels 1–4 will be made on an individual basis and will be determined primarily by a compelling or urgent need for treatment, such as evidence for rapid progression of fibrosis, or deteriorating health status from other comorbidities.

f. Other Criteria for Treatment

In addition to meeting the above criteria for Priority Levels 1–4, inmates being considered for treatment of HCV infection should:

(1) have no contraindications to, or significant drug interactions with, any component of the treatment regimen;

(2) not be pregnant, especially for any regimen that would require ribavirin or interferon;

(3) have sufficient time remaining on their sentence in the DOC to complete a course of treatment;

(4) have a life expectancy > 18 months; and

(5) demonstrate a willingness and an ability to adhere to a structured treatment regimen and to abstain from high-risk activities while incarcerated.

5. The first level of screening patients for treatment with anti-viral medications will occur at the patient's home site. Patients with either:

a. APRI>1.5, or

b. Platelet Count < 100,000 will have an initial review of their medical chart only.

The review will be conducted utilizing the **Hepatitis C Treatment Referral Form (Attachment 20-C)** and will be conducted by the Correctional Health Care Administrator (CHCA), ICN, and Site Medical Director, who will look for the presence of any exclusionary indications listed below.

6. Exclusionary indications include the following:

a. medical exclusions:

(1) an unstable medical condition, to include, but not limited to, cardiopulmonary, cancer, and diabetes. The Site Medical Director will provide clinical information to the Hepatitis C Treatment Committee, which will evaluate and make a determination; and

(2) an undetectable Hepatitis C Quantitative PCR (viral load).

b. administrative exclusions – documented by the CHCA:

(1) current incarceration less than 12 months, unless already taking anti-viral medications;

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(2) expected release from custody within six months;

(3) documented new tattoos during the previous 12 months of incarceration, resulting in a misconduct;

(4) documented positive drug screens during the previous 12 months of incarceration, resulting in a misconduct; and

(5) documented pattern of non-adherence with medical regimens during the previous two months of incarceration.

7. If the CHCA determines that there are no exclusionary indications to anti-viral treatment, the **Hepatitis C Treatment Referral Form** shall be forwarded to the BHCS ICC for further evaluation, possible recommendations for further testing, and initial determination.

I. Hepatitis C Treatment Committee

1. The PA DOC has determined that there is no single method of prioritizing patients for treatment with anti-viral medications. Therefore, the patient's clinical status will be reviewed by a Hepatitis C Treatment Committee, consisting of the PA DOC BHCS Chief of Clinical Services, the Statewide Medical Director for the medical vendor, and the BHCS ICC. Others may be invited to participate on an ad hoc basis.

2. The Committee will utilize the pertinent information available to determine if continued progression through the evaluation process is indicated. The review may include, but will not be limited to, laboratory test trending (INR, AST, albumin, platelet count, bilirubin, etc.), Fibrosure, previous shear wave elastography, liver biopsy, previous treatment results, APRI score, MELD score, and the CTP score. The Committee will also review the stability of any chronic medical and mental health conditions. If the patient is considered a candidate for treatment with anti-viral medication, shear wave elastography will be approved to document the stage of fibrosis/cirrhosis.

3. If the patient meets any of the criteria designated Priority Level 1 – Highest Priority for Treatment, as outlined in **Subsection H.4.a. above**, proceed with the following:

   a. full ultrasound screening for HCC every six months;

   b. EGD for esophageal varices surveillance;

   c. refer to Supervisory Physician for final review and the ordering of DAA medications unless there are contraindications; and

   d. follow in Chronic Care Clinic every month.

4. For those patients approved for elastography, the results will be forwarded to the Committee for review.

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a. Fibrosis Stage 0-2

(1) Repeat Elastography in two years.

(2) Follow in Chronic Care Clinic every six months.

b. Fibrosis Stage 3

(1) Refer to the Supervising Physician for final review and the ordering of DAA medications unless there are contraindications.

(2) Follow in Chronic Care Clinic every three months.

c. Fibrosis Stage 4

(1) Full ultrasound screening for HCC every six months.

(2) EGD for esophageal varices surveillance.

(3) Refer to the Supervising Physician for final review and the ordering of DAA medications unless there are contraindications.

(4) Follow in Chronic Care Clinic every month.

4. The Committee will render its decision and forward the determination, along with follow-up recommendations for those not meeting current priority criteria for greatest need of treatment with anti-viral medications, to the ICN and Site Medical Director, who will then discuss the results with the patient and document the encounter in the **DC-472, Progress Notes**.

5. If the Committee recommends treatment with anti-viral medication, the Site Medical Director will refer the patient to a supervising physician who will direct the anti-viral treatment. The referral will be made utilizing a **Hepatitis C Treatment Referral Form**, to include the following updated laboratory results:

a. genotype, if not already documented;

b. viral load (within one year);

c. HIV (within one year);

d. CMP (within one month);

e. CBC (within one month);

f. abdominal sonogram for patients with cirrhosis (within six months);

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g. as stated in the current contract with the medical vendor, the Supervising Physician must be licensed in Pennsylvania and experienced in the treatment of Hepatitis C utilizing the most current medications. The patient will remain at his/her home institution and treatment will be ordered by the Site Medical Director, under the direction of the Supervising Physician. The Supervising Physician may utilize a Physician Assistant-Certified (PA-C) or a Certified Registered Nurse Practitioner (CRNP), who would be dedicated to the statewide Hepatitis C Program. The Supervising Physician would train and mentor the PA-C or CRNP, and would retain overall treatment responsibility; and

h. the treatment of HCV with anti-viral medications is rapidly evolving. New medications are being approved by the Federal Drug Administration (FDA) frequently. The regimens currently approved by PA DOC will be included in the Diamond Pharmacy Services Formulary for this contract. The Formulary will include all necessary prescribing information and will be updated quarterly via the PA DOC Pharmacy and Therapeutics Committee.

J. References

1. Department of Veterans Affairs National Hepatitis C Resource Center Program, 2014, "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations," accessed July 2015 at http://www.hepatitis.va.gov/provider/guidelines/2014hcv/.

2. Federal Bureau of Prisons, 2016, "Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection," accessed August 2016 at http://www.bop.gov/resources/pdfs/hepatitis_c.pdf.

3. AASLD and IDSA, "Recommendations for Testing, Managing, and Treating Hepatitis C," accessed July 2016 at http://www.hcvguidelines.org.

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